

# **EXHIBIT B**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION

No. 1:19-md-2875-RBK  
Hon. Robert Kugler  
Hon. Joel Schneider

**API MANUFACTURER  
DEFENDANTS' FACT SHEET**

In accordance with Case Management Order No. \_\_, within 60 days of completion of a Defendants' Fact Sheet by the Finished Dose Manufacturer Defendants, the API manufacturer Defendants ("API Manufacturer Defendants") identified in the applicable Plaintiff Fact Sheet ("PFS") must complete and serve this Defendant Fact Sheet ("DFS") on each Plaintiff's counsel identified in the PFS and on the Plaintiffs' Executive Committee through MDL Centrality. Further, no Defendant will be required to serve a DFS until Plaintiff supplies a substantially completed and verified PFS which must provide all of the information requested in section one of the PFS, including but not limited to copies of prescription and/or pharmacy records demonstrating use of a Valsartan-containing drug, and for personal injury Plaintiffs, including a signed HIPAA authorization form and medical records and/or a certification under oath demonstrating that he or she has been diagnosed with the injury claimed in the PFS.

Each response in this DFS must provide the substantive information requested to the extent the information is reasonably accessible to the responding Defendant as maintained in the ordinary course of business, or, if applicable, the responding Defendant may produce or cite to produced documents or business records by Bates number in accordance with Federal Rule of Civil Procedure 33(d).

In filling out this form, Defendants must respond on the basis of information and/or documents that are reasonably available to the Defendant and use the following definitions:

**"AFFECTED DRUGS":** The Valsartan-containing drugs identified in the PFS and confirmed by attached pharmacy records, to the extent lot, batch or other identifiers allow confirmation of drug source. If an API Manufacturer Defendant cannot conclude that they provided the API for an Affected Drug, they shall so state herein.

**"AFFECTED API":** The Valsartan API for any Affected Drug(s).

**"DOCUMENTS":** "Documents" as used in this request is coextensive with the meaning of the terms "documents," "electronically stored information" and "tangible things" as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms. To the extent "Documents" refers to electronically stored information,

the scope shall be interpreted as consistent with the scope of communications contemplated by the Electronic Discovery Protocol (Dkt. 127) agreed to by the parties.

**“PLAINTIFF”:** Means the Plaintiff who took valsartan-containing drugs in the individual action to which this DFS relates.

**“YOU,” “YOUR,” or “YOURS”:** Means the responding Defendant.

I. CASE INFORMATION

This DFS pertains to the following case: \_\_\_\_\_  
Case Name and Docket Number

Date that this DFS was completed: \_\_\_\_\_

Defendant completing this DFS: \_\_\_\_\_

II. API MANUFACTURERS

- A. Based on the information provided by Plaintiff through the PFS and by other Defendants through their responses to the DFS, can you determine that you manufactured Affected API used in any Affected Drug(s)?

Yes \_\_\_\_ No \_\_\_\_

If yes, identify the Affected Drugs you have determined contain Affected API that you manufactured by NDC Code:

- B. If yes, with the information provided by Plaintiff through the PFS and by other Defendants through their responses to the DFS, can you identify the batch or lot number for any Affected API that you manufactured?

Yes \_\_\_\_ No \_\_\_\_

If yes, provide (i) the batch or lot number for the Affected API that you manufactured and identify the corresponding Affected Drug(s); (ii) identify and provide the results of all nitrosamine testing you performed on the Affected API, and (iii) state whether or not the Affected API was recalled and the date of the recall.

- C. For each Affected API listed in response to Question II.A and B, identify whether any dimethylformamide, o xylene, or toluene used in the manufacture of these APIs was recycled or recovered, if so, identify the recycled solvent, the entity(ies) that supplied the solvent, and on which date those solvents were used to manufacture the Affected API.

- D. For each Affected API listed in response to Question II.A and B, provide the date the API was manufactured, the place of manufacture (by facility, city, state/province, and country), and the date of expiry or retest period for the Affected API.
- E. Identify the entity or entities to which you sold or distributed each Affected API listed in response to Question II.A and the date on which each sale or distribution occurred.
- F. State whether you supplied each test result identified in response to Question II.A or B to the FDA, your actual customers, or other Defendants, and, if so, identify the test result and provide the recipient of the test result, date of communication, and content of the communication.
- G. Provide the date(s) on which you sent any recall notice that applied to any Affected API to any Defendants or pharmacies identified in the PFS, or any of your actual or prospective customers of the Affected API listed in response to Question II.A or B, and attach the recall notice(s).
- H. Were any Affected Drugs listed in response to Question II.A or II.B returned to you or retained by you, and does any Affected API listed in response to Question II.B still exist?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please identify and produce:

The date you regained possession or control of the Affected API, if returned to you;

If any, the date and result of any nitrosamine-related testing done on the returned or retained drugs, as by the Court's Order on macro discovery issues (Dkt. 303, ¶ 8); and

The current location of the Affected API.

If not returned to you, but you have knowledge of the location of the drugs, provide the location:

- I. *Answer only if Plaintiffs answered "yes" to question III.B.7 in the PFS:* Have you been contacted through customer call or contact centers by Plaintiff or by anyone acting on behalf of Plaintiff (other than Plaintiff's counsel) at any time from the date Plaintiff began taking valsartan-containing drugs through the present?

Yes \_\_\_\_\_ No \_\_\_\_\_ Don't Know \_\_\_\_\_

If yes, produce all Documents evidencing that contact including video or audio recording of such contacts.

**VERIFICATION**

I am Legal Counsel for \_\_\_\_\_, a Defendant named in this litigation. I am authorized by this Defendant to execute this certification on each corporation's behalf. I hereby certify that the information provided in the accompanying Response to Defendants' Fact Sheet is not within my personal knowledge, but the facts state therein have been assembled by authorized employees and counsel, upon which I relied. I hereby certify, in my authorized capacity, that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of my knowledge on information and belief.

Date: \_\_\_\_\_  
Signature

Name: \_\_\_\_\_

Employer: \_\_\_\_\_

Title: \_\_\_\_\_